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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,128	09/21/2001	Marianne Kearney	49138 (71417)	4197

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/961,128	KEARNEY ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-17 are pending in the application.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: a method for testing a plasmid containing a gene encoding for an endothelial cell mitogen for the ability to produce a biologically active endothelial cell mitogen protein, wherein said gene encode I. acidic and basic fibroblast growth factors, II. vascular endothelial growth factor (VEGF), III. VEGF A, IV. VEGF C, V. epidermal growth factor, VI. transforming growth factor α, VII. transforming growth factor β, VIII. platelet-derived endothelial growth factor, IX. plalatelet-derived growth factor, X. tumor necrosis factor α, XI. hepatocyte growth factor, XII. insulin-like growth factor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 6-10 and 15-17 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
January 19, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

1. A method for testing a plasmid containing a gene encoding for an endothelial cell mitogen for the ability to produce a biologically active endothelial cell mitogen protein comprising:

transiently transfecting a transfection host cell line with a plasmid containing a gene encoding for an endothelial cell mitogen;

incubating endothelial cells with conditioned media from the transiently transfected transfection host cell line; and

determining the level of cell survival of the endothelial cells incubated with conditioned media from the transfection host cell line transfected with the plasmid containing a gene encoding for an endothelial cell mitogen as compared to endothelial cells incubated with conditioned media from the transfection host cell line transfected with a control plasmid;

wherein the level of cell survival of the endothelial cells is determined by the ability of the endothelial cells to reduce MTS to formazan.

2. The method of claim 1, wherein the plasmid contains a gene encoding for an endothelial cell mitogen selected from the group consisting of acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β, platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α, hepatocyte growth factor and insulin-like growth factor.

3. The method of claim 2, wherein the plasmid contains a gene encoding for VEGF.

4. The method of claim 3, wherein the plasmid contains a gene encoding for VEGF A.

5. The method of claim 3, wherein the plasmid contains a gene encoding for VEGF C.

6. The method of claim 1, wherein the transfection host cell line is the Cos-1 cell line.

7. The method of claim 1, wherein the endothelial cells are HUVEC cells.

8. The method of claim 1, wherein the level of cell survival of the endothelial cells incubated with conditioned media from the transfection host cell line transfected with the plasmid containing a gene encoding for an endothelial cell mitogen is at least 25 % fold greater than the level of cell survival of the endothelial cells incubated with conditioned media from the transfection host cell line transfected with the control plasmid.

9. The method of claim 1, wherein the plasmid containing the gene encoding for the endothelial cell mitogen is tested for the ability to produce biologically active endothelial cell mitogen protein prior to use of the plasmid containing the gene encoding for the endothelial cell mitogen in a human gene therapy treatment.

10. A method for evaluating the ability of a first plasmid construct containing a gene encoding for an endothelial cell mitogen to produce a bioactive endothelial cell mitogen protein as compared to the ability of a second plasmid construct containing a gene encoding for an endothelial cell mitogen to produce a bioactive endothelial cell mitogen protein comprising:

transiently transfecting a transfection host cell line with plasmid DNA containing a gene encoding for an endothelial cell mitogen;

incubating endothelial cells with conditioned media from the transiently transfected transfection host cell line; and

determining the level of cell survival of the endothelial cells incubated with conditioned media from the transfection host cell line transfected with plasmid containing a gene encoding for an endothelial cell mitogen;

wherein the level of cell survival of the endothelial cells is determined by the ability of the endothelial cells to reduce MTS to formazan.

11. The method of claim 10, wherein the plasmid contains a gene encoding for an endothelial cell mitogen selected from the group consisting of acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β, platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor α, hepatocyte growth factor and insulin-like growth factor.

12. The method of claim 11, wherein the plasmid contains a gene encoding for VEGF.

13. The method of claim 12, wherein the plasmid contains a gene encoding for VEGF A.

14. The method of claim 12, wherein the plasmid contains a gene encoding for VEGF C.

15. The method of claim 10, wherein the transfection host cell line is the Cos-1 cell line.

16. The method of claim 10, wherein the endothelial cells are HUVEC cells.

17. The method of claim 10, wherein the plasmids containing the gene encoding for an endothelial cell mitogen are being compared as a means for determining an optimal plasmid construct for use in a human gene therapy treatment.